

## REMARKS

### I. Statement

A personal Examiner interview was held on February 22, 2006. The interview was attended by Examiner David J. Isabella and Applicants' representatives, Pierre Kary, Ph.D., Stanislaus Aksman and Victoria A. Silcott. Applicants thank Examiner Isabella for his time and attention.

Currently pending independent claim 1 was discussed in view of Russian Patent No. RU 2,127,129, in the name of Lopatin *et al.* ("the '129 patent"), European Patent No. EP 0727232, issued to Brunstedt *et al.* ("the '232 patent") and European Patent No. EP 0742022, issued to Pavlyk ("the '022 patent"). Applicants' representatives explained that the '129 patent discloses a two-step copolymerization of acrylamide and acrylic acid. They described that when the polymerization of acrylamide is done in alkaline aqueous medium, as is the case in the process disclosed in the '129 patent (*see e.g.*, Translation, page 2, paragraph 5), hydrolysis of the amide occurs, thereby providing carboxylate (when carried out in water, or an ester thereof when carried out in alcohol). This is supported by the first full paragraph on page 49 of the Polymeric Material Encyclopedia (Joseph C. Salamone ed., CRC Press, Inc. 1996), which was shown to the Examiner and is attached as Appendix A for the Examiner's convenience. Applicants' representatives explained the resulting reactions as depicted in Figure 2 of Appendix A: the hydrolysis of acrylamide to acrylic acid (or ester) (II), the polymerization of the acid (or ester) to the amide (III), and the hydrolysis of the amide in the polymer chain to the carboxylate (or an ester thereof) (IV). Applicants' representatives concluded that the content of the carboxylate subunits ("y" in Figure 2) is quite significant, and, though possible, it is highly unlikely that a polymer (*i.e.* more than three consecutive monomers) of acrylamide cross-linked with methylene bis-acrylamide, as claimed by Applicants, is formed. Thus, they asserted that the copolymer of acrylamide and acrylic acid disclosed in the '129 patent does not anticipate the claimed polyacrylamide.

Moreover, the Applicants' representatives stated that the '129 patent teaches away from the claimed invention. For instance, they pointed out that the '129 patent states, "the proposed method permits to decrease the amount of unlinked amino groups (NH<sub>2</sub> radicals) in the polymer . . . in the polymer structure the content of NH<sub>2</sub> radicals is less than 1% of the functional groups total amount." *See* Translation, the paragraph spanning from page 3 to page 4. In

addition, they indicated where the '129 patent also states that a known polyacryl amide gel, as taught in International Application Publication No. WO 81/01290, consisting of acrylamide and methylene bis-acrylamide dissolved in physiological solution polymerized in the presence of polymerization initiators and conducted in one operation "is *not* suitable for use as a soft tissue plastics material, since due to the one-step polymerization process it comprises free NH<sub>2</sub> radical . . ." See Translation, page 4, third full paragraph to fifth full paragraph (emphasis added). Thus, Applicants' representatives submitted that the claimed invention is not obvious in view of the '129 patent.

Furthermore, Applicants' representatives stated that since independent claim 1 is patentable over the '129 patent, then the dependent claims, including claims 46 and 47, are patentable over the '129 patent in view of the '232 patent and the '022 patent.

Finally, Applicants' representatives brought U.S. Reissued Patent No. RE38,913, issued to Pavlyk and submitted in an Information Disclosure Statement on February 13, 2006, to the Examiner's attention since it is now owned by the Assignee of the present application.

Examiner Isabella agreed that the claims are in condition for allowance.

## II. Amendment

Reconsideration of rejections in the Application is respectfully requested. Upon entry of the foregoing amendment, claims 1, 2, 5, 7-12 and 44-53 will be pending. Claims 1, 2, 5, 7-12 and 44-50 stand rejected. Claims 1 and 2 are amended. New claims 51-53 are added.

Applicants respectfully request entry of the above amendment and submit that the amendment does not introduce new matter. Support for the amendment to the claims and for new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. In particular, support for the amendment to claim 1 can be found, *inter alia*, in claim 1 as originally filed. Claim 2 has been amended to depend from independent claims 1 or 51 and is supported, *inter alia*, in the specification at page 6, lines 31-33. New claims 51-53 are directed to alternative embodiments of the invention. Support for claims 51 and 52 can be found, *inter alia*, in the specification at page 5, line 9 to page 6, line 8 and page 7, lines 25-34. Support for claim 53 can be found, *inter alia*, in the specification at page 7, lines 2-4.

Based on the above amendments, the interview and the remarks in this Response, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that they be withdrawn.

**III. Claim Rejections**

Claims 1, 2, 5, 7-12, 44, 45 and 48-50 are rejected under 35 U.S.C. § 102(b) as being anticipated by the '129 patent. Claims 46 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '129 patent and further in view of the '232 patent and the '022 patent.

For all the reasons discussed during the interview and in the Statement above, Applicants respectfully submit that the claims are in condition for allowance and request that the rejections be withdrawn.

### CONCLUSION

For at least the reasons stated above, claims 1, 2, 5, 7-12 and 44-53 are in condition for allowance. Accordingly, Applicants respectfully request that the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to Applicants' undersigned representative to resolve such issues in an expeditious manner.

It is believed that no additional fees are due in connection with this Response. However, in the event it is determined by the U.S. Patent and Trademark Office that additional fees are due, the Commissioner is hereby authorized to charge such fees to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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Dated: February 28, 2005

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# APPENDIX A

# POLYMERIC MATERIALS ENCYCLOPEDIA

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crushed in extruders and dried. In the process of crushing and drying the polymer, antisticking agents (e.g., glycine,  $\beta$ -alanine, polyethylene glycols, and fatty acids) and de-striation stabilizers (e.g., 2-mercaptobenzimidazol, phloroglucinol, and urea) are added. Easily storables, and noncaking polymer gels may be obtained without drying by crushing the polymer gel in mills down to a particle size of 0.2–5 mm and coating the particles with a material poorly wetted by water, such as an active silicon acid, starch, or dextrose.

The polymerization of acrylamide in aqueous solutions in the presence of alkylane agents leads to the obtaining of partially hydrolyzed polyacrylamide. The polymerization process under the action of free radicals ( $R^{\bullet}$ ) (formed upon initiator decomposition) in the presence of an  $\text{OH}^-$  ion formed upon the dissociation of an alkali addition (e.g.,  $\text{NaOH}$ ,  $\text{KOH}$ , and  $\text{LiOH}$ ) and catalyzing the hydrolysis can be described by Equation 2. The reactions II, III, and IV in the process are the main ones. With an increasing concentration of alkali, the rate of polymerization increases and MW decreases. The nature of the hydrolyzing agent and the salt additions influences the acrylamide polymerization process.

#### Precipitation Polymerization

This type of polymerization of acrylamide is conducted in either organic solvents (e.g., acetone, acetonitrile, dioxane, ethanol, tert-butanol, and tetrahydrofuran) or aqueous organic media, which serve as solvents for monomers and as precipitates for polymers. For this reason, at the beginning of the polymerization the reaction mixture is homogeneous, whereas during the process, the precipitation of polymer takes place and the reaction proceeds under heterophase conditions. The commonly used initiators are persulfates, perborates, benzoyl peroxide, and AIBN. In precipitation polymerization the medium never gets very viscous and the polymer is relatively easy to isolate and dry.

The rate of acrylamide polymerization in an acetone-water mixture induced by  $\gamma$ -radiation from a  $^{60}\text{Co}$  source increases up to 20% as the water content increases, whereas MW grows up to 10% with the water content and then remains unchanged for water contents ranging from 30 to 70%. For the conversion degree above 20%, the formation of water-insoluble polymers has been observed due to the imidization. In the case of an acetone-water mixture containing 30–70% acetone, the polymerization is provided with the precipitation of flakes and the formation of coarse lumps is observed. To obtain stable dispersions and prevent the aggregation of flakes, salts are introduced to the reaction mixture. Highly water-soluble acrylamide polymers with  $\text{MW} = 6 \cdot 10^6$ – $10^7$  and high yields are obtained at 20–60 °C from 10–30% acrylamide. The precipitated polymer is filtered and dried.

#### Suspension Polymerization

The initial system is obtained by dispersion (in the form of droplets with diameters of 0.1–5.0 mm) of an aqueous monomer solution in an organic liquid by mechanical stirring in the presence of stabilizers. The dispersion medium may be represented by aromatic and aliphatic saturated hydrocarbons and by mixed hydrocarbons with  $C_6$ – $C_{10}$ . The polymerization is initiated by water-soluble initiators: UV and  $\gamma$ -radiation. The process occurs in droplets of an aqueous monomer solution acting as microreactors, and its kinetics resemble, in some respects solution polymerization, although it is still affected by the stabilizers.

Depending on the hydrophilic-lipophile balance (HLB) of stabilizer, its distribution between aqueous and organic phases, and temperature, the polymerization in suspension may result in a complete phase separation and may occur either with or without the inversion of phases. The nature and concentration of stabilizer influence the rate of polymerization and MW.<sup>5,7</sup> The polymerization rate and MW in

